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FEB 28 2007

Atty Dkt. No.: 10031034-1
USSN: 10/828,907

REMARKS

In view of the following remarks, the Examiner is requested to allow claims 1-16, the only claims pending and under examination in this application.

Formal Matters

Claim 1 has been amended to clarify that a non-cellular chromosome composition is synthesized by mixing pre-determined amounts of individual chromosomes. Support for this amendment can be found in the specification on page 5, lines 13-20 as an exemplary location.

As no new matter has been added by way of this amendment, entry thereof by the Examiner is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bastian et al. (US 2001/0029021 A1).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The claims as amended are directed to a method of assessing a surface-bound polynucleotide, the method including contacting a first labeled population of nucleic acids made from a non-cellular chromosome composition synthesized by mixing pre-determined amounts of individual chromosomes with an array of surface-bound polynucleotides, and evaluating binding of a surface-bound polynucleotide to the first labeled population of nucleic acids relative to binding of a second labeled population of nucleic acids made from a reference chromosome composition.

As such, an element of the pending claims is contacting a first labeled population of nucleic acids with an array, where the first labeled population of nucleic acids is one that is made from a non-cellular chromosome composition which has

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been synthesized by mixing pre-determined amounts of individual chromosomes with an array.

In making this rejection, the Examiner states that Bastian et al. teach how to assess a surface-bound polynucleotide by comparing the ratios of hybridization signals of two different samples, each labeled with two distinguishable labels.

The Applicants respectfully submit that Bastian et al. fail to teach a non-cellular chromosome composition synthesized by mixing pre-determined amounts of individual chromosomes, as claimed. Bastian et al. instead teach a test sample derived from possible tumor tissue and a reference sample derived from normal cells/tissue, labeled with different labels (page 5, paragraph 46). As such, Bastian et al. fail to teach each and every element of the claims.

Accordingly, 1-16 are not anticipated by Bastian et al. under 35 U.S.C. § 102(b) and the rejection may be withdrawn.

Double Patenting

Claims 1-10 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patent Application No. 2005/0233338 A1 ("the '338 patent application") in view of Bastian et al. Applicants respectfully traverse the rejection.

In making this rejection, the Examiner states that the '338 patent application teaches each and every element of the present invention with the exception of using two distinguishable labels, for which element the Examiner turns to Bastian et al.

The claims as amended are directed to a method of assessing a surface-bound polynucleotide, the method including contacting a first labeled population of nucleic acids made from a non-cellular chromosome composition synthesized by mixing pre-determined amounts of individual chromosomes with an array of surface-bound polynucleotides, and evaluating binding of a surface-bound polynucleotide to the first labeled population of nucleic acids relative to binding of a second labeled population of nucleic acids made from a reference chromosome composition.

As such, an element of the pending claims is contacting a first labeled population of nucleic acids with an array, where the first labeled population of nucleic acids is one that is made from a non-cellular chromosome composition which has

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been synthesized by mixing pre-determined amounts of individual chromosomes with an array.

The '338 patent application is silent with regard to a non-cellular chromosome composition synthesized by mixing pre-determined amounts of individual chromosomes, as claimed.

As discussed above, Bastian et al. teach a test sample derived from possible tumor tissue and a reference sample derived from normal cells/tissue, labeled with different labels (page 5, paragraph 46). As such, Bastian et al. fail to teach a non-cellular chromosome composition synthesized by mixing pre-determined amounts of individual chromosomes, as claimed.

Accordingly, since both references are silent with regard to a non-cellular chromosome composition synthesized by mixing pre-determined amounts of individual chromosomes, the combined references do not teach or suggest all of the claim limitations and a *prima facie* case of obviousness is not made. Withdrawal of the rejection is respectfully requested.

Prior Inventorship under 35 U.S.C. § 102

It is alleged that claims 1 and 6-10 are directed to the same invention as that of claims 9-11 of commonly assigned patent US 7011949 B2 ("the '949 patent"), and that the issue of priority under 35 U.S.C. 102 (g) and possibly (f) must therefore be resolved by stating which entity is the prior inventor of the conflicting subject matter.

The Applicants respectfully submit that the cited claims in the '949 patent are silent with regard to a non-cellular chromosome composition synthesized by mixing pre-determined amounts of individual chromosomes, as recited in the claims of the instant application.

As such, the patents are not directed to the same invention and a determination of prior inventorship is not required under 35 U.S.C. 102 (g) or (f). The Applicants respectfully request withdrawal of the rejection.

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Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Mike Beck at (408) 553-3864.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10031034-1.

Respectfully submitted,

Date: February 28, 2007

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